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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,895	03/14/2002	Mark Andrew Guthridge	3991/0K379US0	5422

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EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,895	GUTHRIDGE ET AL.	
	Examiner	Art Unit	
	Zachary C. Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,22,24 and 30-72* is/are pending in the application.

4a) Of the above claim(s) *38,51 and 59-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,22,24,30-37,39-50 and 52-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *21,22,24 and 30-72* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 9/19/05 has been entered in full. Claims 21, 22 and 24 are amended. Claims 1-20, 23 and 25-29 are canceled. New claims 30-72 are added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Sequence Information

The substitute specification has been entered and corrects the defects in compliance with 35 C.F.R1(d) set forth on pg 2 of the 5/17/05 Office Action.

Election/Restrictions

(1) Newly submitted claims 38 and 51 are directed to non-elected species. The elected species of binding motif is the sequence HRSLP (SEQ ID NO: 4) from the receptor GM-CSF/IL-3/IL05. Claims 38 and 51 are directed to a 21 distinct binding motifs (each with a different sequence) each from a different receptor. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38 and 51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

(2) Newly submitted claims 59-72 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The elected group is Group IV of the restriction requirement, drawn to a method of activating cellular activities by regulating the activation of phosphorylation of a binding motif of a receptor. Within this elected group, the species of (1) binding motif: HRSLP and (2) cellular activity: cell survival have been elected. Claims 59-72 are directed to a method of inhibiting cell survival in a cell comprising changing phosphorylation of a binding motif of βc of a receptor capable of binding a cytoplasmic protein and comprising the sequence

–S-X-S/T-. Newly presented claims 59-72 are similar to originally presented claims 26 and 27, which were group V of the restriction requirement, drawn to a method of inhibiting cell survival by an antagonist that binds to the receptor motif. As stated in the restriction requirement of 10/14/2004, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions. The methods are distinct both physically and functionally, and are not required one for the other. The elected invention (group IV) requires search and consideration of a method of activating cellular activities by regulating the activation of phosphorylation of a binding motif of a receptor, which is not required by the other Invention. The newly presented claims (59-72) require search and consideration of a method of inhibiting cell survival (a species of cellular activity), which is not required by the other Invention. Changes that activate or inhibit phosphorylation of a binding motif are distinct changes that will be dependent on different mutations or different molecules (agonist versus antagonist).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 59-72 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

(3) In view of 1 and 2 above, this application contains claims 38, 51 and 59-72 drawn to an invention nonelected with traverse in Applicant's response filed 2/14/05. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

(4) Claims 21, 22, 24, 30-37, 39-50 and 52-58 are under consideration in the instant application, in so far as they are drawn to the elected species: (a) binding motif: HRSLP of the GM-CSF/IL-3/IL-5 receptor and (b) cellular activity: cell survival.

Withdrawn Objections and/or Rejections

The following page numbers refer to the previous Office Action (5/17/05).

The objection to the specification for lacking a descriptive title at pg 4 is *withdrawn* in view of Applicants' amendment to the specification to replace the title.

The rejection of claims 21, 22 and 24 under 35 U.S.C § 112, second paragraph, at pg 11-12 for being indefinite is *withdrawn* in view of Applicants' amendments to the claims.

Please see new claim objections and rejections, below.

Claim Objections

Claims 21, 22, 24, 30-37, 39-49, 52, 53 and 55-58 are objected to because the claims encompass non-elected non-elected species. This was set forth for claims 21, 22 and 24 in the 5/17/05 Office Action and is herewith applied to new claims 30-37, 39-49, 52, 53 and 55-58. Appropriate correction is required.

Applicants' arguments (9/19/05) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response dated 9/19/05 Applicants submit that the claims are generic claims, and that upon allowance of these generic claim, Applicants will be entitled to claims to additional species.

Applicants' arguments have been fully considered but are not found persuasive. The generic claims are not allowed for the reasons set forth previously and maintained in this Office Action. Therefore, the claims remain objected to for encompassing non-elected species.

Claim Rejections - 35 USC § 112, 1st paragraph, scope of enablement

Claims 21, 22, 24, 30-37, 39-50 and 52-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an in vitro method of stimulating hematopoietic cell survival by regulating phosphorylation of a β_c chain, does not reasonably provide enablement for a method of activating or regulating cellular activities by regulating phosphorylation of a binding motif of a receptor or a functional

equivalent or analogue thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments (9/19/05; pg 17-20) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response dated 9/19/05 Applicants discuss the requirements for the test for enablement. The Examiner does not dispute the requirements as characterized by Applicants.

With respect to enablement of the claimed invention, Applicants submit it would require only routine experimentation to identify a binding motif comprising a serine/threonine residue, or comprising the sequence –S-X-S/T-, that is capable of binding a cytoplasmic protein. Applicants submit there are many examples of such binding motifs set forth in the specification. With regard to inoperative embodiments, Applicants submit that the claims require only that regulation of phosphorylation activate at least one activity. Applicants submit it would not require undue experimentation to determine whether a particular receptor could be used to activate a particular cellular activity.

Applicants' arguments have been fully considered but are not found persuasive. The claims are extremely broad because they are directed to a method comprising a multitude of species of receptors, cellular activities, and cell types. The broadest claims encompass any possible receptor that binds a cytoplasmic protein with a binding motif that comprises a serine or threonine residue and is capable of binding a cytoplasmic protein, any possible cellular activity, and possible type of cell. Based solely sequence similarities to the β_c chain, the specification contemplates 21 other species of receptors in addition to GM-CSF/IL-3/IL-5 for which the method can be practiced (pg 22-24). However, the claims also encompass "any receptor that is capable of binding to an extracellular molecule or protein and which mediates its function through the binding of a cytoplasmic molecule or protein such as 14-3-3 protein" (pg 18). The specification (same page) also provides 11 examples of cellular activities that can be activated, including cell survival, proliferation, transformation, differentiation, mitogenesis,

chemotaxis, motility, enhanced phagocytosis, bacterial killing, superoxide production and cytotoxicity, but does not limit the definition of cellular activities to these embodiments. The specification does not limit the type of cell types that may be used in the invention, and therefore the method encompasses any cell type, such as bacterial, yeast, plant or animal cells.

In support of the multitude of combinations of species encompassed, Applicants provide a working example that includes a single species of receptor, cellular activity, and cell type. As described in the previous Office Action, the specification teaches expression of two subunits (the α and β_c chains) of the IL-3 receptor in a CTL-EN mouse cell line. The specification further teaches "while IL-3 was able to promote viability of the CTL-EN cells expressing wtβ_c [wild type β_c chain] for up to 3 days", cells expressing a mutant form of the β_c chain lacking the residue Serine-585 were reduced to 18% viability in three days. The specification teaches that this result (in view of the other results) demonstrates that cell survival of the CTL-EN cells in response to IL-3 requires phosphorylation of the Ser-585 residue. The specification does not demonstrate that this phosphorylation occurs for any other receptor or any other cell type. Applicants have not identified any protein that binds to a binding motif other than the 14-3-3 protein that binds to the β chain binding motif. The specification further teaches that another embodiment encompassed by the claimed invention is inoperative. The specification (Example 8) teaches that "association of 14-3-3 with β_c is important for IL-3 mediated cell survival but not proliferation." 14-3-3 binding is associated with cellular survival but not proliferation. Therefore, using IL-3 to activate proliferation is an inoperative embodiment because phosphorylation of the β_c chain binding motif is not required for proliferation.

In order to practice the claimed invention, one of skill in the art would first need to experiment to determine whether or not each claimed receptor is phosphorylated on a particular binding motif, and that this phosphorylation is associated with binding of a cytoplasmic protein associated with activation of a cellular activity, such as cell survival, This experimentation would need to be repeated for various cell types. Such

experimentation would not be guaranteed of success; other receptors may or may not be phosphorylated on the putative binding motifs and may or may not bind to particular cytoplasmic proteins; these results are unpredictable. The identity of the particular cytoplasmic proteins would need to be identified. While the specification provides examples of twenty-one other receptors that have potential binding motifs similar to the β_c chain, the specification does not teach the correspondence between any of these receptors and particular cellular activities. Because specific receptors are generally involved in specific cellular activities, a skilled artisan would predict that the claimed method would not be operative for a large number of combinations of receptors and cellular activities. As such it would require undue experimentation, rather than routine experimentation, to identify working embodiments encompassed by the claimed methods. Applicants contention that the claims require only that regulation of phosphorylation activate at least one activity is not persuasive because it is not predictable which combination of receptors, cellular activities and cell types will work in the claimed method. Applicants have not identified more than a single working embodiments wherein a cellular activity is activated in response to phosphorylation of a receptor binding motif.

Applicants further submit that in order to expedite prosecution, the claims have been amended to remove the phrase "functional equivalent or analogue thereof".

The Examiner notes that Applicants have amended claims 21, 22 and 24 to remove said the phrase "functional equivalent or analogue thereof". However, while these claims now recite "a receptor", there is no limiting definition of a receptor in the specification such that variants (including mutants with substitutions or deletions to a wild type receptor sequence) are excluded. This is particularly true in that "regulating the activation of phosphorylation" encompasses a broad genus of mechanisms that include mutations in the receptor that regulate activation of the receptor. In view of this, the portion of the rejection in the previous Office Action that was directed to variants of receptors is maintained, and applied to the new claims. Specifically with regard to the β_c chain, Applicants have not provided sufficient guidance as to how to make and use

variant β_c chains that are not 100% identical to a wild type β_c chain, but which still retain the desired property of activating cell survival. While Applicant has taught that mutation of several residues between 582 and 587 results in loss of cell survival, Applicant has not taught what residues in the β_c chain can be mutated and retain cell survival. While it is known that many amino acid substitutions are generally possible in any given protein, the positions within the sequence where such substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and/or receptor oligomerization. These regions can tolerate only relatively conservative substitutions or no substitutions [see Wells (18 September 1990) "Additivity of Mutational Effects in Proteins." Biochemistry **29**(37): 8509-8517; Ngo *et al.* (2 March 1995) "The Protein Folding Problem and Tertiary Structure Prediction, Chapter 14: Computational Complexity Protein Structure Prediction, and the Levinthal Paradox" pp. 492-495; cited in the 5/17/05 Office Action]. Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions.

Furthermore, new claim 42 includes the phrase "functional equivalent or analogue thereof".

With regard to the unpredictability of whether encompassed embodiments are functional, Applicants' response does not address the following additional issues included in the previous Office Action:

1) The claims encompass a method of activating cell survival as performed with the GM-CSF/IL-5/IL-3 receptors expressed in any cell type, for example, any type of bacterial, yeast, plant or animal cell. The specification does not teach whether or not the expression of this receptor in any cell type other than hematopoietic cells will promote cell survival. However, there are numerous types of cells, including bacterial, yeast,

plant, and animal cells (such as HEK293) that do not undergo programmed death. Therefore, in order to practice the full scope of the claimed method, a skilled artisan would need to introduce the receptor in to each of these cell types and then test whether or not cell survival could be stimulated.

2) The claims also encompass a method of activating cell survival as performed with the GM-CSF/IL-5/IL-3 receptors in vitro in a cell-free system or with animal cells located within an organism. The claim encompasses host cells in an organism that naturally express said receptor, or cells genetically engineered to express the receptor, e.g. transgenic organisms or recombinant cells expressing the receptor administered to an organism (gene therapy). The specification teaches that the βc chain of these receptors is phosphorylated and subjected to a 14-3-3 protein associated with cell survival in isolated cells. While this is interesting and worthy of further study, Applicant has not demonstrated that this phosphorylation, binding and associated cell survival would occur in a cell-free system or in cells located within an organism, and it is unpredictable whether or not under these conditions, which are substantially different from those taught by Applicants, and to which Applicants provide no guidance. Furthermore, there are no methods or working examples disclosed in the instant application for creating transgenic multicellular animals that express the receptor, and the unpredictability in the art of creating transgenic animals in very high.

Due to the large quantity of experimentation necessary to test each combination of cell type/receptor type/cellular activity type to determine whether or not it is operative, the lack of direction/guidance presented in the specification regarding operative embodiments, the limited number of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes unpredictability in whether or not embodiments will be operative, and the breadth of the claims which fail to recite any limitations to operative embodiments, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, 1st paragraph, written description

Claims 21, 22, 24, 30-37, 39-50 and 52-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection was set forth for claims 21, 22 and 24 in the 5/17/05 Office Action and is herewith applied to new claims 30-37, 39-50 and 52-58.

Applicants' arguments (9/19/05; pg 20-21) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

Applicants submit that the specification contains sufficient written description of the cellular activities, binding motifs and cells to be used in the claimed method. Applicants submit the specification "contains many representative examples of cellular activities and binding motifs that may be used in the methods of the invention, including relevant functional and structural characteristics of these motifs." Applicants submit the specification teaches a genus of binding motifs and is supported but not limited by the specific examples in the specification. Particularly, Applicants point to 21 examples of receptors with binding motifs. Applicants submit that the specification provides examples of specific amino acid sequences found in the binding motifs, and that a binding motif is identified by the presence of a serine/threonine residue and the ability to bind a cytoplasmic protein which can activate cellular activities. Applicants submit the specification teaches receptors having the binding motif can be found in a diversity of cells other than hematopoietic cells, and submit a list of references and abstracts in support of this contention. Applicants contend that these references show that the invention should not be limited to hematopoietic cells, particularly with respect to IL-3 and GM-CSF and cell survival.

Applicants' arguments, and supporting abstracts, have been fully considered but are not found persuasive. The Examiner does not dispute that receptors, such as the IL-3/GM-CSF receptor, or other receptors with serine/threonine residues, are found in a diversity of cells. However, Applicants have not provided a written description of the

actual phosphorylation state of the binding motif of other receptors, or with the IL-3/GM-CSF β chain in other cells, particularly as it relates to cellular activities such as cell survival. Applicants have only provided a written description of the sequence of said receptors. A statement that that a receptor must be phosphorylated at a particular threonine/serine residue, merely because it has a residue in a sequence with some similarity to that in the IL-3/GM-CSF β chain, is not a written description of the actual phosphorylation state of the residue, and is not a description of whether phosphorylation of said residue is necessary for a particular cellular activity. Furthermore, Applicants have not described the particular intracellular proteins that binding to this particular residue in response to phosphorylation, and have a role in the activated cellular activity. The specification only describes a method comprising hematopoietic cells, one particular receptor subunit (the β_c chain shared by the GM-CSF/IL-5/IL-3 receptors) and the activity of cell survival. The presentation of sequence data and the presence of receptors in other cells does not provide support for the entire genus of cells, receptors, and cellular activities that are encompassed by these claims. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicants were not in possession of the claimed genus.

Claim Rejections - 35 USC § 112, 2nd paragraph

Claims 21, 22, 24, 30-37, 39-50 and 52-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21, 22, 43 and 44 are indefinite because it unclear whether the phrase "capable of binding a cytoplasmic protein" is modifying the "binding motif" or "receptor".

Claims 37 and 50 are indefinite because each recites the following indefinite phrase: "...the receptor is the GM-CSF/IL-3/IL-5 receptor and comprises a sequence which includes amino acids HSRSLP (SEQ ID NO: 4) corresponding to amino acid 582

to 587 of the common βc according to Figure 1 (SEQ ID NO: 1)." This phrase is indefinite because residues 582-587 of the common βc shown in Figure 1, and SEQ ID NO: 1, are KQASSF rather than HSRSLP.

Claim 42 is indefinite because it recites the following indefinite phrase: "...the sequence ^{582}HSRLP^{587} (SEQ ID NO: 4) of the GM-CSF/IL-3/IL-5 receptor..." This phrase is indefinite because residues 582-587 of the common βc shown in Figure 1, and SEQ ID NO: 1, are KQASSF rather than HSRSLP.

Claim 50 is indefinite because it recites the following indefinite phrase: "...said binding motif comprising an amino acid sequence including the sequence ^{582}HSRLP^{587} (SEQ ID NO: 4) of the GM-CSF/IL-3/IL-5 receptor..." This phrase is indefinite because residues 582-587 of the common βc shown in Figure 1, and SEQ ID NO: 1, are KQASSF rather than HSRSLP.

The remaining claims are rejected for depending from an indefinite claim.

Claim Rejections - 35 USC § 102

Claims 21, 22, 24, 30-37, 39-50 and 52-58 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Okuda et al, 1997. Blood. 90(12): 4759-4766. This rejection was set forth for claims 21, 22 and 24 at pg 12-13 of the 5/17/05 Office Action. New claims 30-37, 39-50 and 52-58 are herewith included in this rejection.

Applicants' arguments (9/19/05; pg 22-24) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response dated 9/19/05 Applicants submit that the prior art must teach each and every element of the claimed invention in order to anticipate a claimed invention under § 102. Applicants refer to *Lewmar Marine v. Barient.* Applicants submit that Okuda fails to teach expressly, or inherently, each and every element of the claimed invention. Applicants quote *Continental Can Co. USA, Inc. v Montsanto Co.*, which states that inherency requires "the missing descriptive matter is necessarily present in the reference and that it would be so recognized by persons skilled in the art". Applicants submit that Okuda does not satisfy this requirement because Okuda

only discloses contacting cells with GM-CSF and does not teach or suggest 1) a method for activating a cellular activity by subjecting a binding motif to a cytoplasmic protein that is capable of mediating a cellular activity; or 2) the motif itself.

Applicants' arguments have been fully considered but are not found persuasive. The prior art does not have to teach an element of a claimed invention if the element is an inherently present of the previously described invention. A compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169 USPQ 226 (CCPA 1971)). Applicant is referred to M.P.E.P. 2112 [R-3], which states the requirements of rejection based on inherency. To quote,

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

Furthermore, inherent anticipation does not require that one of ordinary skill in the art recognize an inherent feature in a prior art disclosure (*Schering Corp. v. Geneva Pharmaceuticals Inc.*, 67 USPQ2d 1664 (CAFC 2003); *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)).

In the instant case, it remains that the method of claims 21, 22 and 24 as well as each of the newly presented claims (21, 22, 24, 30-37, 39-50 and 52-58), encompasses a method comprising contacting cells expressing βc chain with GM-CSF, such as taught

by Okuda. The specification specifically teaches that "phosphorylation of the binding motif is caused by the binding of a triggering molecule to its corresponding receptor. Triggering molecules may be cytokines which bind to cytokine receptors...More preferably it is a GM-CSF/IL-5/IL-3 receptor bound by a GM-CSF, IL-5 or IL-3 cytokine" (pg 27) and "cytokines such as GM-CSF, IL-3 or IL-5, will bind to the βc of the receptor. The binding motif of the receptor is then phosphorylated and preferably phosphorylates the 585Ser or equivalent residue. 14-3-3 can bind to the phosphorylated motif thereby positioning the 14-3-3 close to the receptor for further binding of cytoplasmic proteins involved in cell signaling (signaling molecules) for cellular activities such as ... cell survival (pg 29-30)." While Applicants have characterized a previously unappreciated characteristic that occurs during this method (i.e., that a particularly residue is phosphorylated), this characterization does not distinguish the claimed method from that taught by the prior art.

New claims 57 and 58 limit the change to one "introduced by exposing the binding motif to an agonist or antagonist of the binding motif" (claim 57) and "wherein the agonist or antagonist is directed to a serine at position 585 of the common βc according to Figure 1 (SEQ ID NO: 1)." However, the genus of agonists encompassed by these claims includes the GM-CSF molecule of the method of Okuda which binds to the βc chain receptor and results in phosphorylation of the serine at position 585.

Conclusion

No claims are allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch

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